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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/821,229

04/08/2004

Tara Ziolo

5490E-000365

9402

27572

7590

06/20/2006

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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT

PAPER NUMBER

3733

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/821,229

Applicant(s)

ZIOLO ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 163.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 16 is objected to because of the following informalities: In line 5, "of", second occurrence, should be deleted.

Claim 18 is objected to because of the following informalities: There are two periods at the end of the sentence.

Claim 25 is objected to because of the following informalities: In line 2, "prevent" should be changed to --preventing--.

Claim 29 is objected to because of the following informalities: In line 2, "prevent" should be changed to --preventing--.

Claim 41 is objected to because of the following informalities: In line 3, "prevent" should be changed to --prevents--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 recites the limitation "the shaft cam lobe" in the eighth line. There is insufficient antecedent basis for this limitation in the claim.

Claim 17 uses the term "cam lobe", referring both to the cam lobe of the shaft and the cam lobe of expandable head. The applicant's term "shaft cam lobe" and another term for the cam lobe of the expandable head (for example, expandable head cam lobe) would differentiate the two cam lobes.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lombardo et al. (US Pub. 2004/0127896 A1) in view of Konieczynski et al. (US Pub. 2004/0127899 A1).

Lombardo et al. disclose bone fixation apparatus comprising a bone fixation plate (Fig. 1 below) having a fixation hole (Fig. 1 below) and a modular bone fixation fastener received in the fixation hole, the bone fixation fastener including a shaft member (Fig. 1 below) and a head member (Figs. 1 and 31 below), the shaft member having an outer cam at a first end (Fig. 21), the outer cam capable of mating with a corresponding inner cam (Fig. 31) of the head member. The outer cam and the inner cam each have at least one lobe (Figs. 21 and 31). The outer cam and the inner cam each have a plurality of lobes (Figs. 21 and 31). The fixation hole includes a countersunk portion receiving at least a portion of the head member of the bone fixation fastener (Fig. 1 below). Each of the outer and inner cams includes three equidistant lobes (Figs. 21 and 31 below). Fig. 31 shows the inner cam as having more than three equidistant lobes, but three lobes are also possible (paragraph 0010, lines 3-7)). The inner surface of the fixation hole is spherical and engages a spherical outer surface of the head member (Fig. 1 below). The definition of spherical, according to the Merriam-Webster Online Dictionary, is "relating to or dealing with a sphere or its properties". The holes and outer surface of the

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head member relate to a sphere's properties, since they both have some of the features of a sphere. They are both circular and have radii. The fixation fastener is capable of being positioned at a plurality of angles relative to the plate before locking (paragraph 0004, the final sentence). Furthermore, one could position the fastener at virtually any angle before locking the pieces together, since nothing is connected yet (it is not locked). The bone fixation plate includes a viewing window (Fig. 2 below). The bone fixation plate is a spinal fixation plate capable of securing first and second vertebral bodies relative to one another (paragraph 0002, lines 7-12). The bone fixation plate is a spinal fixation plate capable of securing at least three vertebral bodies relative to one another. With the plates three sections (Fig. 1) it is capable of being placed over and capable of securing at least three vertebrae. The bone fixation apparatus comprises at least one aperture receiving an anchoring fastener (Fig. 2 below). The bone fixation apparatus comprises at least another fixation hole receiving another modular fixation fastener (Fig. 1 below). Lombardo discloses a bone fixation apparatus in combination with an insertion and removal tool, the tool comprising a first driver attached to a handle, the driver capable of engaging the head member for rotation of the head member relative to the shaft member (Fig 8A below). The tool comprises a second driver adapted to engage the shaft member for inserting and removing the shaft member to and from a bone portion when the fixation member is not locked (Fig 8A below). Removing the interchangeable head on the drill bit receiving channel 45 would reveal a second driver that is capable of inserting and removing the shaft member. The head of the screw could be drilled in directly if the size of the drill bit receiving channel is the

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right size; if it is the incorrect size the drill bit receiving channel could bore a hole directly in the bone of the patient, and then the drill bit receiving channel could engage the head of the shaft member and push the shaft member into the pre-made hole, and knock the shaft member out of the hole if the shaft member is struck with the drill bit receiving member. Lombardo et al. further disclose a bone fixation apparatus comprising a bone fixation plate (Fig. 1 below) having a fixation hole and a modular bone fixation fastener received in the fixation hole (Fig. 1 below), the bone fixation fastener comprising a shaft member having a head-receiving first end (Fig. 21 below), the first end including a multi-radius outer surface defining a cam lobe (Fig. 21 below) and a head (Fig. 31 below) having a multi-radius inner surface defining a cam lobe (Fig 31 below) capable of mating with the shaft cam lobe. The inner head surface and the outer shaft surface each define a plurality of cam lobes (Figs. 21 and 31 below), which are capable of mating. The inner surface of the fixation hole is spherical and is capable of engaging a spherical outer surface of the head members (Fig. 1 below). The head member can be placed in the hole, and the outer surface of the head member can be placed in contact with the inner surface of the fixation hole. The fixation fastener is capable of being positioned at a plurality of angles relative to the fixation plate when the head member is not expanded. When the head member is not expanded, then the plate is not "locked" to the screw. This allows the fixation fastener to be placed at any angle with respect to the screw. Lombardo further discloses a bone fixation apparatus comprising a bone fixation plate having a fixation hole (Fig. 1 below), the fixation hole having a first diameter in a plane generally parallel to an upper surface of the bone fixation plate (Fig. 1 below), and

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a modular bone fixation fastener received in the fixation hole (Fig. 1 below), the bone fixation fastener including a shaft member (Fig. 21 below) defining a shaft axis and a head member (Fig. 31 below) capable of being carried by the shaft member, the head member capable of rotating about the shaft axis relative to the shaft member between a first position and a second position. The head member can rotate around the shaft member between at least two positions, the locked position and the unlocked position. The head member has a generally spherical outer surface (Fig. 31 below). The fixation hole is generally spherical (Fig. 1 below). The shaft member has a cam capable of mating with a corresponding cam of the head member (Figs. 21 and 31 below).

Lombardo does not disclose the head member being expandable.

Konieczynski et al. disclose a head member that is expandable (Fig 1A below), in order to allow the head member to lock the bone plate to the bone screws (paragraph 0073, lines 1-4).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the head member of Lombardo et al. out of an expandable material as taught by Konieczynski et al, in order to lock the screw to the plate (paragraph 0089, lines 1-3).

The bone fixation apparatus of Lombardo et al. in view of Konieczynski et al. would be inherently capable of performing a method involving: aligning a fixation plate; aligning a first cam to a second mating cam; inserting the modular fastener to one of the bone portions through a hole in the fixation plate; radially expanding a portion of the fastener relative to the hole, to prevent back out of the fastener; selecting the orientation

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of the fastener relative to the fixation plate; rotating the first cam out of alignment relative to the second cam; pressure-locking the fastener to the fixation plate and preventing relative movement between the fixation fastener and the plate; rotating a head member of the modular fastener relative to a shaft of the fastener to expand the head member; rotating the head member to establish a first expanded diameter of the head member; and rotating the head member to establish a second expanded diameter of the head member. The apparatus is capable of performing a method of surgically repairing bone with a fixation plate having a plurality of fixation holes involving: cam-aligning an expandable head member of a modular fastener to a shaft member of the modular fastener; inserting the fastener in one of the fixation holes; radially expanding the head member to prevent back out of the fastener from the fixation hole; pressure locking the head member against the fixation hole, and preventing relative movement between the fixation fastener and the plate; rotating the head member out of cam alignment relative to the shaft member; engaging a portion of the head member with a driver and rotating the driver; unlocking the fixation fastener; unexpanding the head member; removing the fixation fastener; rotating the head member into cam alignment with the shaft member; rotating the head member to establish a first expanded diameter of the head member; rotating the head member to establish a second expanded diameter of the head member.

With regard to statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Lombardo et al. in view of Konieczynski et al., which is capable of being used as claimed if one so

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desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached PTO-892.

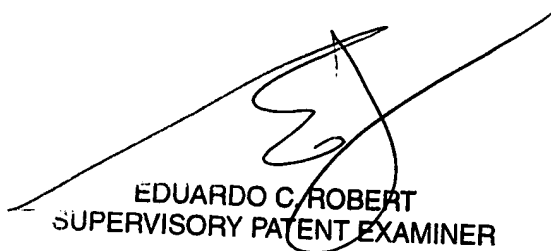
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

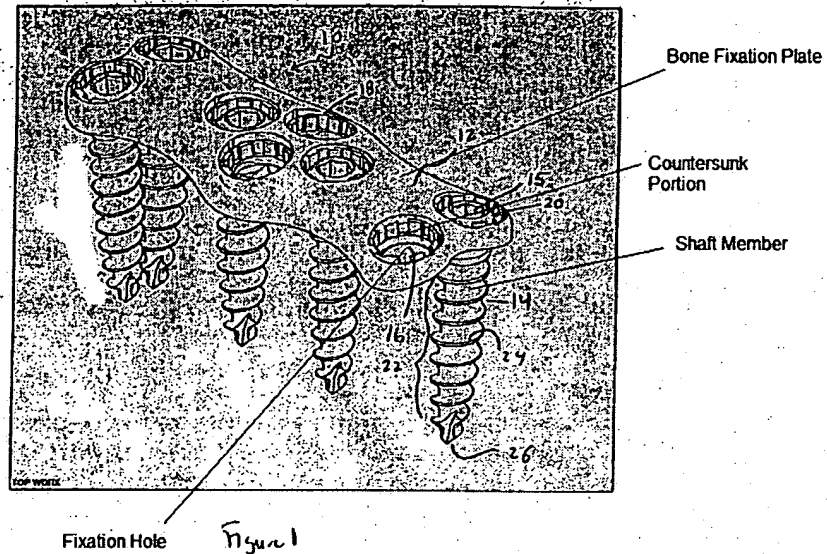
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

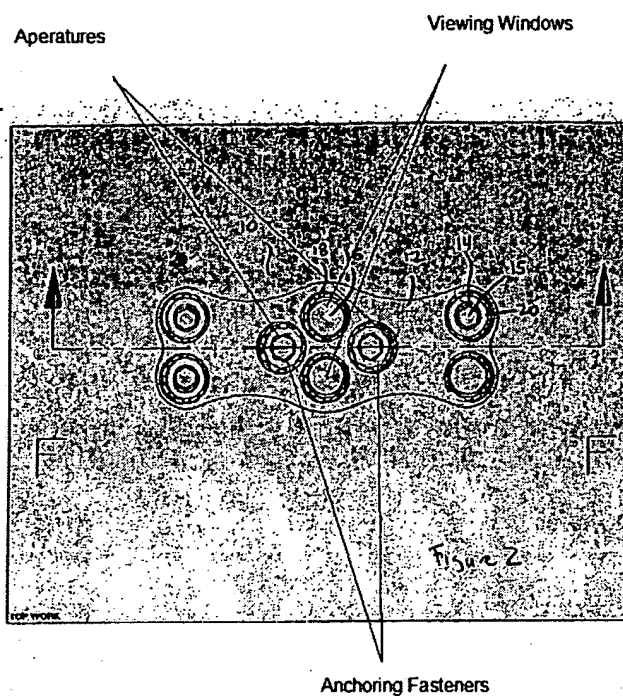
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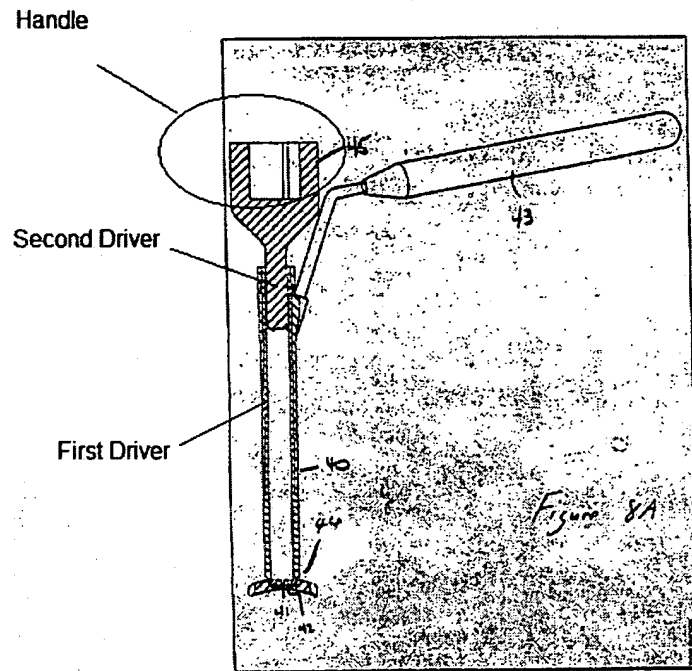


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER



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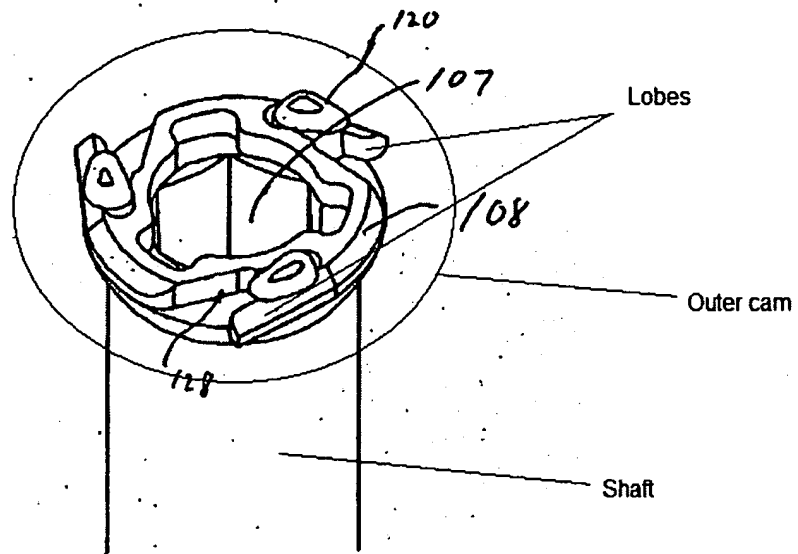


Figure 21

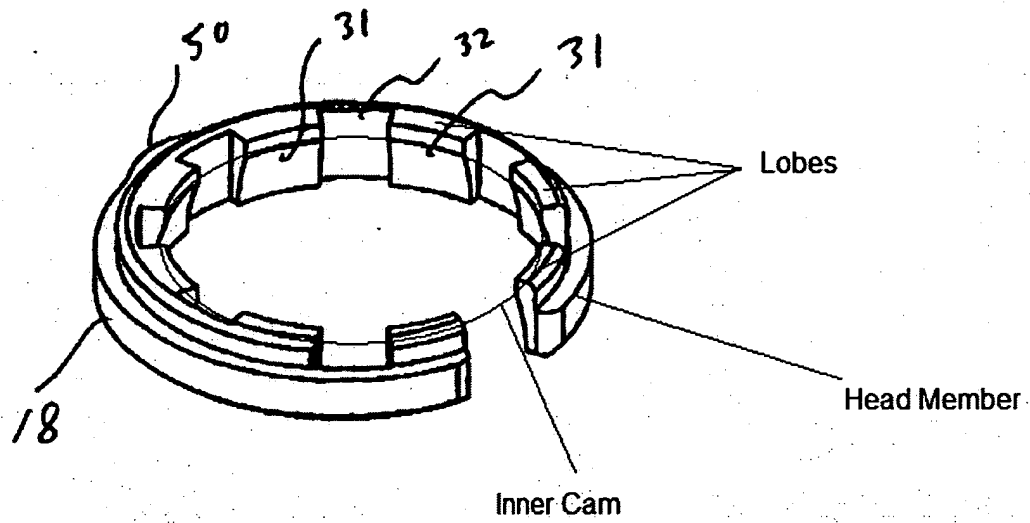


Figure 31

